DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

9/362d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

June 4, 2001

WARNING LETTER

NWE-25-01W

VIA FEDERAL EXPRESSS

Charles M. Nagle, President
John Nagle Company
306 Northern Avenue
Boston, Massachusetts 02210

Dear Mr. Nagle:

We inspected your firm, located at 306 Northern Avenue, Boston, Massachusetts, on April 25 and 26, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your vacuum packed fresh fish to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

As a Domestic Processor

1. You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for vacuum packed/ fresh fish to control the food safety hazard of Clostridium botulinum.

   Processors of vacuum-packed seafood need to consider that all through storage, distribution, display, and consumer handling proper refrigeration, i.e., <38° F, is required to inhibit the growth of Clostridium botulinum type E. It is unlikely that the vacuum-packaged product will remain a <38° F though all these stages of handling. Freezing of the vacuum-packaged product is an acceptable control measure. Beyond freezing, we are not aware of any adequate controls for this type of product

once it leaves the processor. Therefore, in your response to this letter, please explain how the temperature of the product will we maintained until it reaches the final consumer.

2. You must have a HACCP plan that lists the monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fresh tuna does not list the monitoring of Harvest Vessel Records at the Receiving critical control point.

3. You must have a HACCP plan that lists the monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fresh tuna lists a monitoring procedure at the Chilled Storage, critical control point that is not adequate to control histamines. For example, checking the temperature once a day is not adequate.

4. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate with 21 CFR 123.7(b). However, your corrective action for fresh tuna at the Receiving and Chilled Storage critical control point to control histamines is not adequate. For example, at receiving what is "good quality" and a "short period". These terms are subjective. If your product fails to meet the critical limit how are you going to test your product? This comment also holds for at the chilled storage step.

As an Importer

1. You must have product specifications that are designed to ensure that the fish and fishery product(s) you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for vacuum-packed fresh swordfish imported from Chile.

2. You must implement an affirmative step which ensures that the fish and fishery product(s) you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm performed an affirmative step for vacuum-packed fresh swordfish from [redacted] in Chile that was not adequate in that the foreign processor's HACCP plan did not address Clostridum botulinum.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

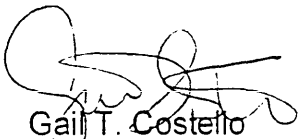
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things your are doing to correct these deviations.

You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice Regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issue in this letter, please contact Mr. Ota at (781) 279-1675.

Sincerely,



Gail T. Costello
District Director
New England District Office